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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/266,346

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JACK L. ARONOWITZ

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER

WINAKUR, ERIC FRANK

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/266,346	<b>Applicant(s)</b> ARONOWITZ ET AL.	
	<b>Examiner</b> Eric F. Winakur	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-15, 21-31, 37 and 42-90 is/are rejected.
- 7) ☒ Claim(s) 7-12, 16-20, 32-36 and 38-41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/03; 2/29/08</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The originally filed claims did not include a claim numbered 28. Further claim numbers 55 and 56 were each used to identify two claims.

Misnumbered claims 29 - 89 have been renumbered 28 - 90.

Applicant is requested to update the claim numbering and corresponding dependencies in conformance with the arrangement noted above when filing a response to this action.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 31, 42 - 45, 57, 58, and 71 - 82 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Angelo et al. (USPN 5,462,064 - cited by Applicant). D'Angelo et al. teach a fluid test patch with optical analysis system. D'Angelo et al. (Figure 3) teach an integrated system for biological fluid constituent analysis that includes a collection

gel layer 8 and a chemical reaction layer 10 that is coated with the specific test reagents and color developer required for any given test. D'Angelo et al. further teach that the arrangement allows a quantity of body fluid sufficient for the chemical test to be absorbed through the skin in a very short time (column 3, lines 9 - 15); one arrangement allowed tests to be performed in ten minutes (column 6, line 65).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 13 - 15, 21 - 30, 56, and 59 - 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo et al. in view of Miffit et al. (USPN 5,179,288 - cited by Applicant). D'Angelo et al. teach a fluid test patch with optical analysis system. D'Angelo et al. (Figure 3) teach an integrated system for biological fluid constituent analysis that includes a collection gel layer 8 and a chemical reaction layer 10 that is coated with the specific test reagents and color developer required for any given test. D'Angelo et al. further teach that the arrangement allows a quantity of body fluid sufficient for the chemical test to be absorbed through the skin in a very short time (column 3, lines 9 - 15); one arrangement allowed tests to be performed in ten minutes (column 6, line 65). Miffit et al. teaches an alternate device for optically measuring a fluid test patch, including features for control of operation of the testing device and processing of the measured values (column 6, line 45 - column 7, line 30; column 8,

lines 29 - 43). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of D'Angelo et al. to include the features of Miffit et al. since this would provide increased accuracy of the measurements.

With regard to claims 14, 15, 21, and 22, it is well known to include components in a housing to provide protection to the elements and/or portability to a system. Without a showing of unexpected results or criticality it would have been obvious to one of ordinary skill in the art at the time of the invention to implement the combination of D'Angelo et al. and Miffit et al. within a hand held or desk top case since it is well known to house components and systems in cases of appropriate size to protect elements of the device and it has generally been held to be within the skill level of the art to implement an arrangement in a well known manner.

6. Claims 46 - 55 and 83 - 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo et al. in view of Ligg Pty. (WO 83/00926 - cited by Applicant). D'Angelo et al. teach a fluid test patch with optical analysis system. D'Angelo et al. (Figure 3) teach an integrated system for biological fluid constituent analysis that includes a collection gel layer 8 and a chemical reaction layer 10 that is coated with the specific test reagents and color developer required for any given test. D'Angelo et al. further teach that the arrangement allows a quantity of body fluid sufficient for the chemical test to be absorbed through the skin in a very short time (column 3, lines 9 - 15); one arrangement allowed tests to be performed in ten minutes (column 6, line 65). Ligg Pty. teaches calibration of a reflectance meter, which is similar to the optical measurement device of D'Angelo et al. (pages 5 - 6). It would have been

obvious to one of ordinary skill in the art at the time of the invention to modify D'Angelo et al. to include calibration of the optical measurement system, as taught by Ligg Pty., since this would provide more accurate measurement results.

7. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo as applied to claim 31 above, and further in view of Ligg Pty. for the reasons given in the paragraph above.

8. Claims 2 - 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo and Miffit et al. as applied to claim 1 above, and further in view of Cheung et al. The combination teaches all of the features of the claimed invention except that wavelength output of the light source is compensated for variation in temperature. Cheung et al. teaches that the output of light sources varies with the temperature of the light source, and a manner to correct for wavelength variations in non-invasive optical measurement arrangements that includes measuring the temperature and mathematically correcting for variations (column 12, line 52- column 14, line 35; column 17, line 9 - column 18, line 47). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify D'Angelo and Miffit et al. to include compensation for variation of wavelength output, as taught by Cheung et al. to provide more accurate results.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo and Miffit et al. as applied to claim 1 above, and further in view of Farkas et al. The combination teaches all of the features of the claimed invention except that wavelength output of the light source is compensated for variation in temperature. Farkas et al.

teaches that the output of light sources varies with the temperature of the light source, and a manner to correct for wavelength variations in non-invasive optical measurement arrangements that includes using a measured voltage drop in correcting for errors (column 1, line 37 - column 2, line 53; column 5, line 18 - column 6, line 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify D'Angelo and Miffit et al. to include compensation for variation of wavelength output, as taught by Farkas et al. to provide more accurate results.

***Allowable Subject Matter***

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest a measurement arrangement that includes any of a transistor for setting a quiescent operating point and generating a second differential signal; means for mounting at least two light emitting diodes in an orientation to minimize specular reflections to a detector; a patch and reader configuration of claim 16; means for processing a first output to generate a feedback signal related to ambient light detected by an optical detector; or means for calibrating that includes means for setting a reflectometer to read a certain DC output voltage at a mid-point, in combination with the other claimed elements.

11. Claims 7 - 10, 16 - 20, 32 - 36, and 38 - 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant is reminded that the numbering of certain of these claims must be updated, per the requirement of paragraph 1 above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571/272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768